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Product Hopping 2.0: Getting the FDA To Yank Your Original License Beats Stacking Patents

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ARTICLES

PRODUCT HOPPING 2.0: GETTING THE FDA TO YANK YOUR ORIGINAL LICENSE BEATS STACKING PATENTS

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INTRODUCTION

Approved by the Food and Drug Administration (FDA) in 1995, extended-release oxycodone (OxyContin[®]) became a blockbuster drug for its manufacturer Purdue Pharma. Fifteen years later, the company secured approval of an abuse-resistant formulation of this product (OxyContin OP[®]). From the perspective of legitimate users of this opioid analgesic, OxyContin OP offers absolutely no advantages over the classic recipe; from a public health perspective, however, the new formulation appears to reduce serious risks to illegitimate users. In 2013, just as its contested patents on OxyContin expired, Purdue managed to persuade the FDA to withdraw its license for the original formulation, which prevented the introduction of generic copies of the older version that otherwise would have undercut sales of OxyContin OP.

Pharmaceutical manufacturers routinely introduce new and improved versions of successful drugs as their patents on older products wind down and generic rivals prepare to enter the market, which antitrust scholars have denominated as “product hopping.” Part I elaborates on this phenomenon. The recent experience with the reformulation of OxyContin, as detailed in Part II, represents an extreme variant of such arguably anticompetitive behavior. By virtue of the FDA’s withdrawal of the license for OxyContin, patients who derive no benefit from the abuse-resistant features will not enjoy the option of using cheaper generic versions of the older product, instead having to pay a premium for the new formulation over the next decade or so. The agency’s decision may well make sense in this context, but, to the extent that it signals a more general willingness to act favorably upon withdrawal requests by license holders whenever they introduce modified versions of their products, the FDA may have given brand-name drug manufacturers a powerful new mechanism for further delaying generic entry.

I. A PRIMER ON PRODUCT HOPPING IN THE PHARMACEUTICAL INDUSTRY

“Product hopping” refers to line extensions and affiliated strategies used by brand-name drug manufacturers to retain market share once generic competition becomes a threat.¹ This practice poses antitrust concerns insofar

1. See Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016–17, 1020–21 (2010); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685, 709–17 (2009); Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472, 1487–89 (2008); M. Sean Royall et al., *Antitrust Scrutiny of Pharmaceutical “Product Hopping,”* ANTITRUST, Fall 2013, at 71; see also Alan Devlin & Michael Jacobs, *Anticompetitive Innovation and the Quality of Invention*, 27 BERKELEY TECH. L.J. 1, 47 (2012) (“[P]roduct hopping is today one of the most controversial practices at the intersection of antitrust and intellectual property”); Alan Devlin, *Exclusionary Strategies in the Hatch-*

as it effectively allows companies to extend their monopolies even after their original patents have expired.² Drug product hopping can happen in several ways. For instance, manufacturers may introduce—and seek additional patent protections for—sustained release formulations that require less frequent dosing or a slightly modified form of the active ingredient with purportedly greater safety or effectiveness.³ So-called “patent stacking” or “evergreening” happens with some frequency in the pharmaceutical industry,⁴ though courts often invalidate these efforts to extend intellectual property protections.⁵

Waxman Context, 2007 MICH. ST. L. REV. 631, 658 (crediting Herbert Hovenkamp with coining the term); Julie Appleby, *New Scrutiny of Drugmakers*, WASH. POST, Mar. 19, 2015, at A14.

2. See Dogan & Lemley, *supra* note 1, at 715–17; Steve D. Shadowen et al., *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1, 44–58, 80–81 (2009); Seth Silber & Kara Kuritz, *Product Switching in the Pharmaceutical Industry: Ripe for Antitrust Scrutiny?*, 7 J. GENERIC MEDS. 119, 124–29 (2010); see also Carrier, *supra* note 1, at 1024–36 (focusing on line extensions introduced before the expiration of contested patents but after settlements of patent infringement litigation that stall generic entry on the original formulation); Cheng, *supra* note 1, at 1497–515 (arguing that the antitrust concerns with product hopping have merit in only limited circumstances).

3. See Shadowen et al., *supra* note 2, at 22–44 (offering a detailed empirical account of the range and timing of drug product reformulations, which totaled 425 over the nearly 15 year study period); Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 HOUS. J. HEALTH L. & POL’Y 379, 388–405 (2007) (discussing reformulations of the molecular entity (by isolating metabolites, enantiomers, or polymorphs), new dosage forms or routes of administration, and additional indications for use); Melody Petersen, *New Medicines Seldom Contain Anything New, Study Finds*, N.Y. TIMES, May 29, 2002, at C1; Duff Wilson, *As Generics Near, Makers Tweak Erectile Drugs*, N.Y. TIMES, Apr. 14, 2011, at B1. Such behavior occurs in other industries as well. See, e.g., *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp.*, 592 F.3d 991, 1000–02 (9th Cir. 2010) (rejecting antitrust claims against the dominant supplier of pulse oximeters for introducing new devices when patents on older monitors expired and it faced competition from suppliers of compatible sensors); Brianna M. Schonenberg, Comment, *Twenty Years in the Making: Transitioning Patented Seed Traits into the Generic Market*, 97 MARQ. L. REV. 1039, 1057–60, 1070–71 (2014) (discussing efforts to switch farmers to Monsanto’s second-generation Roundup Ready seeds).

4. See C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 619–23 (2011); Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, 7 PLOS ONE e49470 (2012); Julie Appleby & Jayne O’Donnell, *Consumers Pay as Drug Firms Fight over Generics*, USA TODAY, June 6, 2002, at 1A (“The average number of patents on a drug has gone from two to 10 in the past two decades, according to the generic-drug industry.”); Melody Petersen, *Lilly Set Back in Patent Case over Prozac*, N.Y. TIMES, Aug. 10, 2000, at C1 (“Efforts to extend the monopoly on a popular brand-name drug are common in the pharmaceutical industry. . . . [O]ften companies file numerous patent applications on different aspects of the same drug—different uses of the drug, for example, or slightly different formulations—to try to get even more years of exclusive sales.”); see also Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 HEALTH AFF. 2286, 2291 (2012) (“The 108 patents we identified could extend the market exclusivity of [Abbott’s] ritonavir and lopinavir/ritonavir to at least 2028—twelve years after the expiration of the patents on their base compounds . . .”).

5. See, e.g., *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010)

Entirely apart from patents, however, market exclusivity periods granted by licensing agencies such as the FDA represent important incentives for innovative activity.⁶ New chemical entities generally receive a five-year period of market exclusivity after securing agency approval for a new drug application (NDA),⁷ which protects the brand-name manufacturer from generic competition during that time even if it exceeds the remaining terms of any patents.⁸ If the NDA sponsor has to undertake additional investigations in order to secure supplemental approval for changes in a previously licensed drug's formulation or labeling, then it may receive three additional years of protection but only with regard to the modified features of the drug product.⁹

Because the extra three years of market exclusivity for modifications in the formulation or labeling of a brand-name drug would not prevent approval

(invalidating method-of-use patent for Gemzar[®] (gemcitabine) as a cancer treatment); *id.* at 1386 (“[O]bviousness-type double patenting encompasses any use for a compound that is disclosed in the specification [as a utility] of an earlier patent claiming the compound and is later claimed as a method of using that compound.”); *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1378–82 (Fed. Cir. 2003) (affirming a decision that the compound claims in the patent for desloratadine (Clarinex[®]), a metabolite formed upon ingestion of loratadine (Claritin[®]), were invalid because inherently anticipated by prior art even though not disclosed in the earlier (and now expired) compound patent for loratadine); *see also* Christine S. Paine, Comment, *Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production Through Patent Layering*, 33 SETON HALL L. REV. 479, 497–506 (2002) (reviewing earlier litigation).

6. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 347–48 (2007); *id.* at 359–61, 364–66 (calling market exclusivity periods administered by the FDA “pseudo-patents”); *id.* at 387–88 (“Regulatory sources of exclusivity have become more important as development times for new drugs have lengthened, cutting further into product patent terms, and as industry ‘evergreening’ strategies to secure additional follow-on patents have encountered obstacles in the courts.”); William E. Ridgway, Note, *Realizing Two-Tiered Innovation Policy Through Drug Regulation*, 58 STAN. L. REV. 1221, 1235–36 (2006) (explaining that this form of quasi-IP protection has become increasingly important).

7. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (2012); 21 C.F.R. § 314.108(b)(2) (2014).

8. Conversely, if patents extend beyond this exclusivity period, then generic manufacturers filing an application for abbreviated new drug approval (ANDA) must either delay launch until after patent expiration or file a certification that the brand-name manufacturer’s listed patents are invalid (or would not be infringed), which in turn entitles the patent holder to file an infringement action and trigger an automatic 30-month stay on FDA approval of the ANDA (unless a court rules sooner). *See* 21 U.S.C. § 355(j)(5)(B)(iii). In effect, therefore, the manufacturer of a new chemical entity covered by patent(s) later held to be invalid would not have to fear any generic competition for more than seven years after securing agency approval. For further details about the operation of these and other forms of FDA-mediated market exclusivity periods, *see* LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 1007–36 (3d ed. 2012).

9. *See* 21 U.S.C. § 355(j)(5)(F)(iii)-(iv); 21 C.F.R. § 314.108(b)(5)(ii). In contrast, biological products enjoy a twelve year exclusivity period, but FDA approval of a reformulated or relabeled version does not entitle the sponsor to an extension unless the reformulation entailed a modification to the structure of the product that results in a change to its safety, purity, or potency. *See* *Biologics Price Competition and Innovation Act of 2009*, Pub. L. No. 111-148, Title VII(A), § 7002, 124 Stat. 804, 807–08 (2010) (codified at 42 U.S.C. § 262(k)(7)(C)(ii) (2012)).

of an abbreviated new drug application (ANDA) referencing the original product,¹⁰ sponsors may take additional steps to guard against the prospect that generic competition will undercut their purportedly new and improved products. For instance, after securing supplemental approval for a new use of a previously licensed drug (with the new use protected by three years of market exclusivity and possibly also a method patent), a brand-name manufacturer might remove the originally approved indication(s) from the drug's labeling in an effort to prevent FDA approval of ANDAs for those original use(s). In light of this opportunity for anticompetitive manipulation, the agency explained that such a maneuver would prevent generic approval only if the NDA sponsor removed the original use(s) for reasons of safety or effectiveness.¹¹

In the event of a reformulation, switching the original drug to over-the-counter (OTC) status may have a similar effect. The FDA may allow a brand-name company to revise the labeling for an older formulation to permit its use without the need for a prescription. AstraZeneca did this shortly after introducing Nexium® (esomeprazole magnesium) for gastroesophageal reflux disease just as its blockbuster drug Prilosec® (omeprazole) faced generic competition.¹² If switching the older drug brings with it three years of market exclusivity, this would prevent generic competition on the now over-the-counter (OTC) product with its revised labeling.¹³ Even without any extended exclusivity for the OTC version, generic competitors could only compete in the nonprescription marketplace,¹⁴ thereby giving the reformulated

10. See *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1496, 1499–500 (D.C. Cir. 1996); see also *Sigma-Tau Pharm., Inc. v. Schwetz*, 288 F.3d 141, 145–48 (4th Cir. 2002) (same, in connection with “orphan” drug exclusivity).

11. See Draft Guidance for Industry on Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications, 65 Fed. Reg. 64,225 (Oct. 26, 2000). For more on the nature of agency guidance documents (especially those that it never finalizes), see Lars Noah, *Governance by the Backdoor: Administrative Law(lessness?) at the FDA*, 93 NEB. L. REV. 89, 97–105 (2014).

12. See Daniel I. Gorlin, *Staving off Death: A Case Study of the Pharmaceutical Industry's Strategies to Protect Blockbuster Franchises*, 63 FOOD & DRUG L.J. 823, 839–49 (2008). Persistent shortages of OTC Prilosec led some observers to suspect that the manufacturer had done this intentionally in order to increase the demand for Rx Nexium. See Alex Berenson, *Where Has All the Prilosec Gone?*, N.Y. TIMES, Mar. 2, 2005, at C1; Sarah Ellison & Jeanne Whalen, *Prilosec Scarcity Puts Spotlight on a P&G-AstraZeneca Pact*, WALL ST. J., Feb. 7, 2005, at B2.

13. See Lars Noah, *Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?*, 19 HARV. J.L. & TECH. 359, 390 (2006) (“When sponsors file supplements with supporting research in pursuit of an Rx-to-OTC switch, this right has additional value insofar as it normally would prevent altogether the marketing of generic versions of the original prescription product and entirely delay generic versions of the new OTC product for three years.”); Diedra Henderson, *No-Competition Drugs Stir Controversy*, BOS. GLOBE, Nov. 13, 2006, at E1.

14. See Opportunity for Hearing on a Proposal to Withdraw Approval of Prescription Polyethylene Glycol 3350 Abbreviated New Drug Applications, 73 Fed. Reg. 63,491, 63,491–92

prescription product what amounts to an extended monopoly.

The actions of Abbott Laboratories with regard to TriCor[®] (fenofibrate) have become something of a *cause célèbre* among antitrust commentators.¹⁵ Abbott had discontinued all sales of the original (capsule) formulation of this drug for lowering cholesterol and triglycerides in an effort to switch prescribers to their newer (slightly lower dose tablet) formulation.¹⁶ In the resulting antitrust litigation, the federal district court denied Abbott's motion to dismiss after making much of the fact that the company had gone to great lengths to remove all traces of TriCor capsules from the marketplace as soon as its tablet form became available.¹⁷ Two years later, in contrast, a different district court dismissed antitrust claims filed against AstraZeneca, emphasizing that the company had not entirely ceased marketing Prilosec

(Oct. 24, 2008); *id.* at 63,493 n.1 (explaining exceptions where a version of the original product remained subject to prescription-only use); *see also* Noah, *supra* note 13, at 385 ("It might promote clarity to understand such switches as a two-step process: the FDA revokes the NDA for the original drug, which carried prescription labeling, but offers to issue a new (though financially less desirable) license for an OTC version of the same drug as a substitute.").

15. *See* Carrier, *supra* note 1, at 1019–20, 1029–30 n.149; Dogan & Lemley, *supra* note 1, at 712–17; Silber & Kuritz, *supra* note 2, at 121–23; Cheng, *supra* note 1, at 1491–94, 1496–99, 1510–12; *see also* Devlin & Jacobs, *supra* note 1, at 43 (calling this case "the poster child for the campaign to condemn product hopping"); Shadowen et al., *supra* note 2, at 1 n.* (disclosing that all three of the authors had worked on behalf of the plaintiffs in the TriCor litigation); *id.* at 62–65 (discussing the case).

16. *See* Shirley S. Wang, *TriCor Case May Illuminate Patent Limits*, WALL ST. J., June 2, 2008, at B1 (reporting that the FTC was also investigating); *see also* Royall et al., *supra* note 1, at 74–75 (comparing antitrust claims filed by a generic competitor against Warner Chilcott after taking similar steps with its acne drug Doryx[®]). Actavis recently announced plans to withdraw Namenda[®] (memantine) almost one year before patent expiration so that existing patients would have to switch to its newer extended-release version, which would make switching them back upon generic entry more difficult. *See* Andrew Pollack, *New York Files an Antitrust Suit Against the Maker of an Alzheimer's Drug*, N.Y. TIMES, Sept. 16, 2014, at B3 (comparing the company's tactics with the TriCor case); *see also* Andrew Pollack, *Judge Rules Drug Maker Can't Shelve Old Pill*, N.Y. TIMES, Dec. 12, 2014, at B6 (reporting that a federal judge hearing an antitrust lawsuit filed by the state of New York had issued a preliminary injunction against the company).

17. *See* Abbott Labs. v. Teva Pharms. USA, Inc., 432 F. Supp. 2d 408, 416–18 (D. Del. 2006) (noting also a subsequent change in dosage and directions for use by dropping a need to take with food, repurchases of previously distributed inventory in order to prevent continued dispensing of refillable prescriptions, and a switch in the code for the older formulations in the privately managed National Drug Data File to "obsolete"); *id.* at 421–24 (declining to dismiss antitrust claims because the defendants had effectively prevented purchasers from selecting the older formulations and the plaintiff might be able to prove that the anticompetitive effects of the reformulations outweighed their benefits); *see also* Jonathan D. Rockoff, *Abbott, Teva Reach a Deal to Delay a Generic TriCor*, WALL ST. J., Dec. 1, 2009, at B5 ("Abbott agreed to pay \$184 million to settle litigation alleging that the company modified TriCor to prevent pharmacists from automatically substituting generic equivalents, a practice known as 'product switching.'"); *id.* (reporting that "Abbott is trying to shift TriCor users to a new, branded version called TriLipix that was approved late last year").

when it introduced Nexium.¹⁸

Unilateral withdrawal of an older brand-name product—coupled with its removal from the FDA’s list known as the *Orange Book*—would complicate but not prevent the approval of generic versions.¹⁹ This represents a subtle but important point utterly lost on some commentators.²⁰ To be sure, Abbott’s promotional efforts would have shifted physician prescribing patterns in favor

18. See *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 148–49, 151–53 (D.D.C. 2008) (finding no plausible harm from the fact that the manufacturer had ceased advertising its original prescription formulation and soon thereafter largely switched it OTC); *id.* at 152 (“The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action.”); see also Shadowen, *supra* note 2, at 42 (“[O]ne court has suggested that the only product changes of antitrust concern are those in which the manufacturer switched products and then also entirely withdrew the original product from the market.”); *cf. id.* at 67–75, 78–79 (disagreeing with this view as too restrictive).

19. See 21 U.S.C. § 355(j)(4)(I), (6) (2012) (barring approval of a pending ANDA—and requiring withdrawal of a previously approved ANDA—if the reference listed drug (RLD) was withdrawn for reasons of safety or effectiveness); Abbreviated New Drug Approval Regulations, 57 Fed. Reg. 17,950, 17,990 (Apr. 28, 1992) (codified at 21 C.F.R. § 314.122(a) (2014)) (“An abbreviated new drug application that refers to . . . a listed drug that has been voluntarily withdrawn from sale in the United States must be accompanied by a petition seeking a determination whether the listed drug was withdrawn for safety or effectiveness reasons.”); see also *Cumberland Pharm. Inc. v. FDA*, 981 F. Supp. 2d 38, 43–46, 48–53 (D.D.C. 2013) (affirming the agency’s conclusion that the petitioner had not withdrawn its original formulation for safety reasons, which meant that the FDA acted lawfully in approving a generic version of that product, even though the agency previously had urged the petitioner to investigate the necessity of an inactive ingredient in the original formulation because of its potential allergenicity, which prompted the company to introduce a reformulated product that excluded this ingredient); *ISTA Pharms., Inc. v. FDA*, 898 F. Supp. 2d 227, 232 (D.D.C. 2012) (calling objections to an ANDA referencing the original product after the brand-name manufacturer had unilaterally withdrawn it in favor of a reformulated version “a poorly-disguised gambit to avoid competition, game the drug-approval system, and maintain a monopoly over the bromfenac eyedrop market”); *In re Reglan/Metoclopramide Litig.*, 74 A.3d 221, 223 (Pa. Super. Ct. 2013) (“[A]fter [ANDA approvals], the RLD holder discontinued marketing its drug, and the FDA withdrew approval. Under applicable regulations, the FDA was empowered to fill the void left by the withdrawn RLD by designating one of the generic manufacturers to serve as a substitute.”), *appeal denied*, 99 A.3d 926 (Pa. 2014); Shadowen et al., *supra* note 2, at 70 (“[N]either cannibalizing a product nor withdrawing it from the market prevents the FDA from approving the generic of the original product or prevents doctors from writing prescriptions for it.”).

20. See Devlin, *supra* note 1, at 658 (“[I]f the [generic] company wants to market an identical version of the [unilaterally withdrawn] drug for which it originally sought an ANDA, it will now have to submit an NDA.”); Devlin & Jacobs, *supra* note 1, at 49 (same); Yoshitani & Cooper, *supra* note 3, at 399–400 (explaining incorrectly that the reformulation of the contraceptive Ovcon 35[®] into a chewable tablet coupled with the manufacturer’s removal of its NDA listing for the older tablet (that could only be swallowed) from the *Orange Book* would bar generic entry on the latter dosage form); Michelle L. Ethier, Note, *Permissible Product Hopping: Why a Per Se Legal Rule Barring Antitrust Liability Is Necessary to Protect Future Innovation in the Pharmaceutical Industry*, 3 AKRON INTELL. PROP. J. 323, 335 (2009) (repeating Mr. Devlin’s error); see also *infra* notes 53–54 and accompanying text (elaborating).

of the new formulation,²¹ and this switch would have foreclosed the possibility of generic substitution at the point of dispensing by pharmacists. Physicians remained entirely free, however, to prescribe the original formulation then available only from generic manufacturers,²² and perhaps they would have done so because of restrictions in the formularies of their patients' drug benefit plans.²³ As revealed in the next Part, Purdue managed

21. See Mark A. Hurwitz & Richard E. Caves, *Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals*, 31 J.L. & ECON. 299, 302, 317–18 (1988); Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 430–33 & n.257 (2002). Indeed, a manufacturer could encourage such switching without altogether discontinuing its original version. See Andrew Pollack, *A Drug's Second Act: Battling Jet Lag*, N.Y. TIMES, Jan. 7, 2010, at B1 (discussing Cephalon's efforts to extend its Provigil® (modafinil) franchise by, prior to patent expiration, halting all promotional efforts, substantially increasing its price and introducing the relatively less expensive extended-release drug Nuvigil® (armodafinil) with additional indications); Jonathan D. Rockoff, *How a Drug Maker Tries to Outwit Generics*, WALL ST. J., Nov. 18, 2008, at B1 ("Some health-plan managers say it will likely be too costly for them to keep patients on Provigil once Nuvigil is introduced in 2009 because cheaper generic versions of Provigil will still be more than two years off."); cf. John Carreyrou, *Inside Abbott's Tactics to Protect AIDS Drug—Older Pill's Price Hike Helps Sales of Flagship; A Probe in Illinois*, WALL ST. J., Jan. 3, 2007, at A1 (discussing a manufacturer's efforts to encourage use of its protease inhibitor combination Kaletra® (lopinavir/ritonavir) by dramatically increasing the price of one of its components when sold separately as Norvir® (and used in combination with other brand-name manufacturer's drugs), adding that this option seemed less likely to garner bad press than withdrawing Norvir from the market altogether).

22. See Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 FOOD & DRUG L.J. 249, 254–55 (2007); cf. Shadowen et al., *supra* note 2, at 51–52 (dismissing this theoretical prospect as largely unrealistic). Although entitled to a different form of intellectual property protection, which means that they face no real threat of generic competition, and not subject to any form of regulatory licensing, textbooks offer a rough parallel: producers respond to the growing supply of used copies by introducing new editions that may or may not contain substantially new content (new editions of my casebook, cited in *supra* note 8, always do); when instructors decide whether to adopt a new edition, they often do not care about the differences in price (and, to the extent that they care more about having to revise their class notes, instructors may be more willing to transition to barely improved new editions, while students might find it inconvenient if not worse to purchase a used copy of the previous edition when enrolled in such a course). In the end, however, instructors who do pay attention to the financial burden on their students—perhaps because institutions may encourage them to do so when selecting textbooks—can continue using older editions so long as adequate supplies of used copies remain available for their students to purchase.

23. See Frank J. Ascione et al., *Historical Overview of Generic Medication Policy*, 41 J. AM. PHARMACEUTICAL ASS'N 567, 573–74 (2001); Daniel A. Crane, *Provigil: A Commentary*, 3 HASTINGS SCI. & TECH. L.J. 453, 454–55 (2011); Milt Freudenheim, *Not Quite What Doctor Ordered: Drug Substitutions Add to Discord over Managed Care*, N.Y. TIMES, Oct. 8, 1996, at D1. But cf. Shadowen et al., *supra* note 2, at 19 ("Despite [managed care organizations'] theoretical ability to use disadvantaged formulary placement and other tactics to defeat anticompetitive product reformulations, they have not done so."). Thus, when generic versions of one drug in a therapeutic class become available, other similar drugs may lose significant market share even though still patent protected. See Scott Hensley, *Side Effects: As Generics Pummel Its Drugs, Pfizer Faces Uncertain Future*, WALL ST. J., Jan. 5, 2006, at A1.

to eliminate even that last avenue of potential competition when it reformulated OxyContin, and the company managed to do so in a way that would largely escape antitrust scrutiny.²⁴

II. NEW & IMPROVED PRODUCT HOPPING: THE OXYCONTIN MANEUVER

Over the last two decades, the opioid analgesic OxyContin has followed a decidedly convoluted path, hardly typical of other blockbuster drugs. The latest interesting twist in this still unfolding story happened in 2013 when the FDA decided that generic competitors could not yet enter the marketplace. The particulars may interest only those steeped in this somewhat arcane regulatory field, but this case study touches on important broader themes related to public health and patient welfare.²⁵ It also illustrates a novel twist on the product hopping phenomenon in the pharmaceutical industry.

Approved by the FDA in 1995, OxyContin quickly (and somewhat unexpectedly) became the most widely prescribed narcotic painkiller in the United States; by its fifth anniversary on the market, the drug generated more than \$1 billion annually for its manufacturer Purdue Pharma.²⁶ Although regulated by the FDA as a “new drug” (and by the Drug Enforcement Administration as a Schedule II controlled substance), it represented little more than a new formulation of long-used (and abused) oxycodone hydrochloride, a synthetic form of morphine effective in relieving severe or chronic pain such as that experienced by cancer patients. Older painkillers such as Percocet[®] and Percodan[®] also contain oxycodone, but OxyContin used a slow-release mechanism designed to offer sustained relief over a twelve-hour period to patients with chronic moderate to severe pain. In contrast, the older drug products in this class (including the related hydrocodone drugs such as Vicodin[®] and Lortab[®]) may offer uneven relief over just a four-hour period.²⁷

The extended-release formulation also seemed to make OxyContin less prone to abuse because it would not provide a quick euphoric effect upon

24. Generally, when a private party successfully petitions the government to render a decision that has the effect of restraining competition, antitrust laws have no application. See *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 379–82 (1991); Dogan & Lemley, *supra* note 1, at 706–07 & n.91.

25. See Lars Noah, *Challenges in the Federal Regulation of Pain Management Technologies*, 31 J.L. MED. & ETHICS 55, 63–64 (2003).

26. See Chris Adams, *Painkiller's Sales Far Exceeded Maker's Plans—Purdue Pharma Scrambled to Expand Its Production of OxyContin Medication*, WALL ST. J., May 16, 2002, at D2. In contrast, Purdue's newer extended-release hydromorphone product (Palladone[®]) spent less than a year on the market before its withdrawal because of serious risks that it posed to patients. See Marc Kaufman, *Painkiller Palladone Pulled over Alcohol Risk*, WASH. POST, July 14, 2005, at A14.

27. See Paul Tough, *The Alchemy of OxyContin*, N.Y. TIMES MAG., July 29, 2001, at 32.

initial ingestion. As a result, Purdue widely promoted its drug as presenting a lower risk of addiction and diversion.²⁸ The company apparently failed, however, to anticipate the creativity of drug abusers. To defeat the slow-release feature, these individuals chewed, crushed, dissolved, or scraped the coating off of the tablets, leaving stronger dosages of oxycodone than found in individual Percocet or Percodan tablets.²⁹ They then ingested, snorted, or injected the substance. Reports suggest that thousands of people have died after overdosing in this fashion,³⁰ and data from the Centers for Disease Control and Prevention (CDC) indicate that most of the deaths and other injuries linked to this and similar drugs have occurred in persons other than legitimate patients.³¹

Some critics alleged that Purdue had over-promoted OxyContin for the treatment of temporary or less serious pain,³² arguing that this led to overprescribing, thereby creating a larger supply for potential diversion.³³ The company also evidently underplayed the hazards faced by patients who used the drug as intended.³⁴ In 2001, responding to patterns of irresponsible prescribing, the FDA demanded that OxyContin's package insert add a black-box warning.³⁵ This represented part of a risk-management plan that also included a mechanism for tracking suspected sources of diversion, educating

28. See Barry Meier & Eric Lipton, *Under Attack, Drug Maker Turned to Giuliani for Help*, N.Y. TIMES, Dec. 28, 2007, at A1.

29. See generally BARRY MEIER, PAIN KILLER: A "WONDER" DRUG'S TRAIL OF ADDICTION AND DEATH (2003).

30. See Lisa Girion et al., *Drugs Now Deadlier Than Autos; Fueled by Highly Addictive Prescription Pain Medications, Fatal Overdoses Have Surpassed Traffic Deaths Nationwide*, L.A. TIMES, Sept. 18, 2011, at A1; see also Leonard Paulozzi et al., *CDC Grand Rounds: Prescription Drug Overdoses—A U.S. Epidemic*, 61 MORBIDITY & MORTALITY WKLY. REP. 10, 10 (2012) ("Since 2003, more overdose deaths have involved opioid analgesics than heroin and cocaine combined . . .").

31. See Charles Ornstein & Tracy Weber, *Ties Between Drugmakers, Advocacy Groups Probed*, WASH. POST, May 9, 2012, at A2; see also Aron J. Hall et al., *Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities*, 300 JAMA 2613, 2616–17 (2008) (finding, in a study of overdose deaths in West Virginia over a five-year period, that 93% involved opioid analgesics and that the majority of victims had not secured these with a valid prescription).

32. See Mark A. Ford, Note, *Another Use of OxyContin: The Case for Enhancing Liability for Off-Label Drug Marketing*, 83 B.U. L. REV. 429 (2003); Phillip J. Wininger, Note, *Pharmaceutical Overpromotion Liability: The Legal Battle over Rural Prescription Drug Abuse*, 93 KY. L.J. 269 (2004-2005). Courts generally have, however, rejected negligent marketing claims involving OxyContin. See, e.g., *Labzda v. Purdue Pharma L.P.*, 292 F. Supp. 2d 1346, 1355 (S.D. Fla. 2003).

33. See U.S. GEN. ACCOUNTING OFFICE, GAO-04-110, PRESCRIPTION DRUGS: OXYCONTIN ABUSE AND DIVERSION AND EFFORTS TO ADDRESS THE PROBLEM (2003).

34. See Carrie Johnson, *OxyContin Makers Admit Deception: Addiction Danger from Painkiller Was Understated*, WASH. POST, May 11, 2007, at A1.

35. See Josh White, *More Warnings About OxyContin; FDA, Drugmaker Advise Caution in Prescribing Addictive Painkiller*, WASH. POST, July 26, 2001, at B2.

physicians, and supplying special prescription pads.³⁶ By 2008, the FDA directed Purdue to cease claiming that there was only a small risk of addiction in patients.³⁷ Meanwhile, the Justice Department brought misbranding prosecutions, and Purdue paid \$600 million to settle claims asserted by numerous parties after pleading guilty to felony charges for fraudulently claiming that OxyContin was less prone to abuse.³⁸

As Purdue's regulatory market exclusivity period wound down, a pair of other companies filed applications with the FDA seeking approval of generic versions of OxyContin. Because it had secured patents that ran until roughly 2013 (extending well beyond its market exclusivity period),³⁹ Purdue initiated infringement litigation to prevent premature FDA approval of these copycats. Then, in 2004, after one of its patent lawsuits initially failed,⁴⁰ Purdue filed a petition with the FDA asking that the agency not approve generic versions until those potential competitors had established abuse-management programs comparable to its own.⁴¹ A few months later, the FDA approved a pair of

36. See Anna Wilde Mathews & Gary Fields, *Federal Agencies Seek to Curb Abuse of Potent Painkillers*, WALL ST. J., Dec. 3, 2003, at B1.

37. See Peter Whoriskey, *The Prescription Painkiller Binge*, WASH. POST, Dec. 31, 2012, at A1.

38. See *United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 572–73, 576 (W.D. Va. 2007) (accepting plea agreements by the company as well as three high-ranking corporate officers each of whom received sentences of three years of probation and together paid \$34.5 million in fines); Barry Meier, *3 Officials Are Sentenced in Case Involving OxyContin*, N.Y. TIMES, July 21, 2007, at C4; see also *Friedman v. Sebelius*, 686 F.3d 813, 828 (D.C. Cir. 2012) (reversing and remanding orders excluding these officers from participating in federal health care programs for 12 years).

39. See *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 98 F. Supp. 2d 362, 367–70, 400 (S.D.N.Y. 2000) (summarizing the patents, and granting a preliminary injunction on patent infringement claims after a competitor received FDA approval of a full NDA for a controlled-release oxycodone product), *aff'd*, 237 F.3d 1359, 1368 (Fed. Cir. 2001). One decade later, with less than a year of patent protection remaining, Purdue belatedly initiated a pediatric study in the hopes of receiving six months of extra market exclusivity. See Barry Meier, *After Delay, OxyContin's Use in Young Under Study*, N.Y. TIMES, July 7, 2012, at B1.

40. See *Purdue Pharma L.P. v. Endo Pharm. Inc.*, No. 00–CV–8029, 2004 WL 26523, at *27 (S.D.N.Y. Jan. 5, 2004) (declining to enforce Purdue's patents due to inequitable conduct during their prosecution before the PTO).

41. See Gardiner Harris, *OxyContin Manufacturer Seeks Delay of Rival Drugs*, N.Y. TIMES, Jan. 13, 2004, at C2; see also Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 287–88 (2012) (discussing Purdue's request as an illustration of a pattern of behavior increasingly engaged in by brand-name drug manufacturers); Marc Kaufman, *Petitions to FDA Sometimes Delay Generic Drugs: Critics Say Companies Misusing Process*, WASH. POST, July 3, 2006, at A1 (elaborating on this tactic); cf. Alicia Mundy, *Senate Panel Hits Sanofi Payments*, WALL ST. J., May 25, 2011, at B3 (reporting that the manufacturer of Lovenox® (enoxaparin sodium) had contributed more than \$5 million to medical groups who then agreed to file a purportedly independent citizen petition with the FDA questioning (though unsuccessfully) the bioequivalence of a proposed generic version of this blockbuster anticoagulant). See generally Matthew Avery et al., *The Antitrust Implications of Filing "Sham" Citizen Petitions with the FDA*,

ANDAs subject to that condition, though the pending appeal of the patent litigation made launching the generic products a risky proposition at that time.⁴² Ultimately, the appellate court largely sided with Purdue,⁴³ which meant a further delay for these competitors.

After the filing of several tort lawsuits,⁴⁴ and under pressure from federal and state government officials,⁴⁵ Purdue began to work on an abuse-resistant formulation of its flagship product. Originally, it considered adding a sequestered opioid antagonist (such as naltrexone) that could counteract the oxycodone when crushed.⁴⁶ Ultimately, Purdue decided to harden the tablets by infusing them with a polymer (polyethylene oxide); even if still crushed, the powdery interior would become jelly-like when added to water. In 2010, more than two years after submitting an application for this reformulation to the FDA, Purdue received approval for OxyContin OP[®].⁴⁷

As a line extension that required additional studies, OxyContin OP received three years of market exclusivity,⁴⁸ though patents covering this reformulation extended much longer—until 2025.⁴⁹ Even if a court ultimately found the patents for OxyContin OP invalid, the mere fact that the

65 HASTINGS L.J. 113, 124–26, 132–40 (2013); Lars Noah, *Sham Petitioning as a Threat to the Integrity of the Regulatory Process*, 74 N.C. L. REV. 1 (1995).

42. See Anna Wilde Mathews & Leila Abboud, *FDA Approves Generic OxyContin*, WALL ST. J., Mar. 24, 2004, at A3. Nonetheless, generic versions did compete against the brand-name product for a few years. See Drew Buono, *New Delivery Systems Advance Pain Management Medications*, DRUG STORE NEWS, Apr. 21, 2008, at 32, available at 2008 WLNR 25523741.

43. See *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1135–37 (Fed. Cir. 2006).

44. See Joseph B. Prater, Comment, *West Virginia's Painful Settlement: How the OxyContin Phenomenon and Unconventional Theories of Tort Liability May Make Pharmaceutical Companies Liable for Black Markets*, 100 NW. U. L. REV. 1409, 1418 (2006) (“By late 2003, OxyContin was the source of nearly 300 state and federal lawsuits against Purdue . . .”). For a comprehensive recent review of the various lawsuits related to OxyContin, see Richard C. Ausness, *The Role of Litigation in the Fight Against Prescription Drug Abuse*, 116 W. VA. L. REV. 1117 (2014).

45. See Barry Meier, *U.S. Asks Painkiller Maker to Help Curb Wide Abuse*, N.Y. TIMES, May 1, 2001, at A16; see also Ausness, *supra* note 44, at 1146–57 (discussing civil and criminal claims against Purdue brought by state and federal officials); *id.* at 1163–65 (concluding that this public litigation has had a somewhat greater impact than private lawsuits).

46. See Barry Meier, *Maker Chose Not to Use a Drug Abuse Safeguard*, N.Y. TIMES, Aug. 13, 2001, at A11. Along similar lines, some had suggested including a chemical irritant such as capsaicin. See Sandra Blakeslee, *Drug Makers Hope to Kill the Kick in Pain Relief*, N.Y. TIMES, Apr. 20, 2004, at F1.

47. See Abby Goodnough & Katie Zezima, *Drug Is Harder to Abuse, but Users Persevere*, N.Y. TIMES, June 16, 2011, at A21; see also Lisa Girion, *FDA Approves Recast Painkiller; Experts Are Wary of a Drug Called a Less-Addictive Form of OxyContin*, L.A. TIMES, July 24, 2014, at AA1 (“Purdue Pharma’s Targiniq ER combines a long-acting form of the opioid analgesic oxycodone with the medication naloxone, which is commonly used to reverse the effects of an opioid overdose.”).

48. See *supra* note 9 and accompanying text.

49. See Timothy W. Martin, *Generic OxyContin Pains the FDA—Patent Expiration Brings Debate over Abuse Deterrents*, WALL ST. J., Apr. 15, 2013, at B1.

manufacturer had listed them would forestall FDA approval of any generics for a few more years past the end of the new exclusivity period.⁵⁰ Normally, however, the agency would allow generic versions of the older formulation on the market,⁵¹ but in this case that did not happen; on the very day that Purdue's initial patents expired and the previously approved generics would have launched, the agency withdrew its approval for original OxyContin on safety grounds.⁵²

Only once before has the FDA granted a request from a brand-name company simply to revoke the license for an older version of a drug,⁵³ which effectively pulls the rug out from under potential generic competitors. In 2003, the agency withdrew Tegison® (etretinate), four years after its sponsor had begun marketing a safer version.⁵⁴ If Purdue's recent similar experience

50. See *supra* note 8.

51. See *supra* notes 9–10 and accompanying text.

52. See Barry Meier, *F.D.A. Bars Generic OxyContin*, N.Y. TIMES, Apr. 17, 2013, at B1. In contrast, just one month later, the FDA rejected a similar request from Endo Pharmaceuticals after that company introduced a reformulated version of its extended-release oxymorphone product (Opana ER®) because the agency found the new drug no better at deterring abuse. See Timothy W. Martin, *FDA Says Pain Pill Still Easy to Abuse*, WALL ST. J., May 11, 2013, at B4; Katie Thomas, *F.D.A. Rejects Request to Keep Generic Rivals of Painkiller off the Market*, N.Y. TIMES, May 11, 2013, at B3.

53. Cf. Shadowen et al., *supra* note 2, at 43 tbl.7 (identifying three instances of a brand-name manufacturer withdrawing an original formulation near generic entry—TriCor, Versed, Zithromax—even though none of these involved FDA withdrawal of the license); *id.* at 57–58 (offering Hytrin as a fourth such example though not included in their survey because its reformulation from tablet to capsule occurred before 1995). An OTC switch amounts to a partial license withdrawal, see *supra* note 14, but Purdue obviously could not have done that with OxyContin. The FDA may, of course, remove brand-name prescription drugs (and with it the possibility of generic competition on those drugs) once serious safety questions arise or safer substitutes from other manufacturers become available. See, e.g., Removal of Nomifensine Maleate from List of Approved Drug Products, 51 Fed. Reg. 21,981, 21,982 (June 17, 1986) (“As a consequence of the removal [of the antidepressant Merital for reasons of safety], ANDA’s will not be accepted for the drug.”); Denise Grady, *Doctors Call for Caution on Two More Diabetes Drugs*, N.Y. TIMES, May 20, 2000, at A10 (Rezulin®); Gardiner Harris, *Studies Lead to Withdrawal of Drug for Bowel Ailment*, N.Y. TIMES, Mar. 31, 2007, at A12 (Zelnorm®); *Findings*, WASH. POST, Mar. 30, 2007, at A8 (reporting that the FDA requested the withdrawal of the Parkinson’s disease drug pergolide, a dopamine agonist, because it had been associated with heart valve damage since 2002 and “[t]here are other drugs in the same class that can be substituted”).

54. See Lars Noah, *Too High a Price for Some Drugs?: The FDA Burdens Reproductive Choice*, 44 SAN DIEGO L. REV. 231, 238 (2007); cf. Bruce Ingersoll, *FDA Proposes to Force Seldane Off the Market*, WALL ST. J., Jan. 14, 1997, at B1 (reporting that the agency initiated a proposal—over the manufacturer’s objections—to withdraw Seldane® (terfenadine), less than two weeks after authorizing generic entry, because six months earlier it had approved a reformulated and safer version sold as Allegra® (fexofenadine) by the same manufacturer). Interestingly, the previously mentioned survey that had treated discontinued marketing as instances of “withdrawal” (and found three such cases during the period studied) had failed to include Tegison in this category, see Shadowen et al., *supra* note 2, at 43 tbl.7, even though the authors separately had discussed this reformulation as an instance of metabolite switching, see *id.* at 25 n.74.

indicates that the FDA has become more willing to entertain such withdrawal petitions,⁵⁵ it offers a potentially enticing new opportunity for anticompetitive behavior. Then again, in light of the growing tendency of courts to impose liability on manufacturers of brand-name drugs for injuries caused by their generic rivals,⁵⁶ innovator companies may have an obligation to prevent any further sales of now obsolete drugs after introducing a genuinely new and improved reformulation.⁵⁷

The FDA has no power to demand that Purdue license its patents on the reformulated drug to others. On the contrary, the company has jealously guarded its franchise, initiating numerous lawsuits to prevent the use of its new abuse-resistant formulation by generic competitors.⁵⁸ The problem differs from another type of intellectual property question that has arisen in this setting—where generic sellers must closely track the labeling for a brand-name drug, courts have rejected copyright infringement claims brought by the latter.⁵⁹ Similarly, when the Celgene Corporation created its complex risk management program for Thalomid[®] (thalidomide) to guard against the risk of birth defects, it secured patents on it—and, when the four manufacturers of isotretinoin (Roche's Accutane[®]) had to create a similar program, they managed to purchase licenses from Celgene.⁶⁰ Of course, because Celgene did not compete in the acne drug marketplace, it had no reason to resist these licensing agreements.⁶¹

55. See David Sell, *Endo Pharmaceuticals Fails in Maneuver to Have Own Drug Called Unsafe*, PHILA. INQUIRER, Dec. 21, 2012, at A27.

56. See, e.g., *Wyeth, Inc. v. Weeks*, No. 1101397, 2014 WL 4055813 (Ala. Aug. 15, 2014); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 309–18 (Ct. App. 2008).

57. See Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INSUR. PRAC. L.J. 673, 680 (2010); cf. Linda A. Johnson, *Wyeth Sues FDA to Block Generic Rival of Antibiotic Zosyn*, BOS. GLOBE, Sept. 24, 2009, at 10 (summarizing objections to the agency's approval of a generic version of an older formulation that the brand-name manufacturer had discontinued four years earlier after it added a pair of ingredients to guard against the possibility of a dangerous chemical reaction).

58. See Timothy W. Martin, *OxyContin Maker Guards Exclusivity*, WALL ST. J., June 28, 2012, at A1.

59. See *SmithKline Beecham v. Watson Pharm., Inc.*, 211 F.3d 21 (2d Cir. 2000).

60. See Lars Noah, *This Is Your Products Liability Restatement on Drugs*, 74 BROOK. L. REV. 839, 888 (2009).

61. In contrast, Celgene has faced criticism for refusing to supply samples of Thalomid and Revlimid, which also faces stringent distribution restrictions to guard against birth defects, to generic manufacturers that need them in order to engage in bioequivalence testing necessary for seeking FDA approval. See Dina ElBoghdady, *Generic-Drug Makers' Complaints Prompt Inquiries*, WASH. POST, May 23, 2012, at A15; Katie Thomas, *Game Plan Against Generics*, N.Y. TIMES, Apr. 16, 2013, at B1; cf. 21 U.S.C. § 355-1(f)(8) (2012) ("No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an . . . abbreviated new drug application."); Shashank Upadhye & Braden Lang, *The FDA and Patent, Antitrust, and Property Takings Laws: Strange Bedfellows Useful to Unblock*

Even if Congress gave the FDA some power to facilitate generic competition in such circumstances, the agency would have had no real incentive to do so insofar as price reductions for opioid analgesics might further expand the black market.⁶² In contrast, after a company launched a new drug for preterm labor at what struck many as an exorbitant price, FDA officials threatened to undercut the brand-name manufacturer's exclusivity rights by either allowing premature generic competition or tolerating pharmacy compounding,⁶³ and a federal court declined to entertain a challenge to the agency's announcement.⁶⁴ In the case of slow-release oxycodone, the FDA seems untroubled by the fact that it has deferred the prospect of generic competition for as much as a dozen more years, and Purdue need not fear any antitrust litigation by virtue of the agency's decision.⁶⁵

For legitimate patients, OxyContin OP represents no improvement over the original formula. On the contrary, the FDA's decision to withdraw the license for OxyContin contemporaneously with approval of the reformulated version ensures that, for at least another decade, patients will have to pay extra for features that they neither want nor need. Indeed, if agency licensing of other off-patent opioid analgesics that include abuse-resistant features will come with similar withdrawals of previously approved versions, then it gives brand-name companies an incentive to develop such products and charge legitimate patients a premium.⁶⁶

Although it seems entirely sensible to remove more easily abused and far cheaper generics, we should not lose sight of the barely visible trade-off that

Access to Blocked Drugs, 20 B.U. J. SCI. & TECH. L. 84, 95–100 (2014) (discussing the limited apparent force of this provision).

62. See Devlin Barrett et al., *U.S. on Alert for Canadian Drugs*, WALL ST. J., Dec. 5, 2012, at A2.

63. See Rob Stein, *Price Tag Soars on Preterm Birth Drug*, WASH. POST, Mar. 29, 2011, at A1.

64. See *K-V Pharm. Co. v. FDA*, 889 F. Supp. 2d 119 (D.D.C. 2012).

65. See *supra* note 24. Of course, the FDA's withdrawal decision provides powerful endorsement of the sponsor's claim that a reformulated product represents a genuine improvement over the older drug. Conversely, a decision by the FDA to reject such a request (or perhaps a failure by a sponsor to even make one) may indicate that a reformulation represents a trivial advance done primarily to fend off generic competition. In short, the availability of this regulatory maneuver could help courts undertake the rule-of-reason analysis when drug reformulations trigger antitrust claims.

66. See Timothy W. Martin & Jonathan D. Rockoff, *Race Accelerates for Safer Painkiller*, WALL ST. J., May 6, 2013, at B1; see also Lisa Girion, *Powerful Painkiller Approved*, L.A. TIMES, Nov. 21, 2014, at A8 (reporting that the FDA approved Purdue's abuse-resistant extended-release hydrocodone drug (Hysingla ER[®]), and noting speculation that this might persuade the agency to withdraw its controversial recent approval of the lower-dose pure hydrocodone drug Zohydro[®] that lacks such safeguards).

the FDA has made in this case.⁶⁷ “Law-enforcement officials have long been concerned about the potential for a bigger, cheaper, less well-controlled supply once versions of OxyContin are marketed by multiple companies,” but, when the FDA tentatively approved generic versions of OxyContin a decade ago, it reportedly “didn’t believe that the availability of generic versions would increase demand for the drug . . . [while it] may cut the cost for legitimate patients.”⁶⁸ Of course, an abuse-resistant option did not exist at the time, but the agency’s recent change of heart apparently elevates public health and law enforcement needs over the interests of patients for whom cost may pose a genuine barrier to access.

CONCLUSION

Purdue’s successful maneuver may well inspire manufacturers of other drugs to seek FDA withdrawal of their licenses for older versions in order to block approval of generic copies of the original, which otherwise would have threatened to undercut sales of newly approved formulations. If antitrust objections lodged against less complete efforts at product hopping have merit, then the license withdrawal strategy surely magnifies concerns about illegitimate monopolization. Then again, to the extent that the license holder successfully persuades the FDA that its line extension offers genuine improvements that render the original formulation obsolete, antitrust laws would have no application. The agency must, therefore, carefully guard against the possibility of anticompetitive manipulation of this process.

67. See Timothy W. Martin, *FDA Blocks Generic Versions of OxyContin*, WALL ST. J., Apr. 17, 2013, at B3; cf. David M. Kent et al., *New and Dis-improved: On the Evaluation and Use of Less Effective, Less Expensive Medical Interventions*, 24 MED. DECISION MAKING 281, 282 (2004) (“Although lower quality, lower cost products are ubiquitous in most consumer markets, barriers remain for . . . cost-saving medical technologies.”).

68. Mathews & Abboud, *supra* note 42, at A3.